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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/143,503	08/28/1998	ROBERT D. AINSWORTH	11770	3597

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EXAMINER	
KENNEDY, SHARON E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/143,503 90/004946	Applicant(s) AINSWORTH ET AL.
	Examiner Sharon E. Kennedy	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Claim Objections

Claims 1-64 are objected to because of the following informalities: The claims are not in proper reissue format. See 37 CFR 1.173(b). Appropriate correction is required.

Specifically, applicant submitted a "clean copy" of the claims and additional claims 57-64. There is no copy of the claims and the amendments made vis a vis the original patent. Further, applicant used the claim identifier "pending." This is not accepted further does not offer any useful information to the examiner.

Regarding new claims 57-64, ALL of the claim should be underlined, including the claim number. It is strongly recommended that applicant use the claim identifier "new" for these claims.

The following would be proper claim format for applicant's claim 58.

Claim 58. (New) The catheter of claim 57, wherein said extruded thermoplastic polymeric material comprises a polyetheretherketone.

Regarding claims 1-6, these are the claims from the original patent. The identifier "pending" may not be used. It is strongly recommended that applicant use "original" to identify these claims. For example, applicant's claim 2 should have presented as follows:

2. (Original) The balloon dilatation catheter of claim 1 wherein the polymeric material is a linear aromatic polymer.

Regarding claims 7-17, these are claims from the re-examination certificate B1 5,554,121. The following portion of MPEP 1453 is relevant for these claims.

> (C) For a reissue application, where a certificate of correction has issued for the patent: An amendment in the reissue application must be presented as if the changes made to the original patent text via the certificate of correction are a part of the original patent. Thus, all text added by certificate of correction is presented in the amendment (made in the reissue application) without italics. Further, any text deleted by certificate of correction is entirely omitted in the amendment (made in the reissue application).

Accordingly, applicant's claims 7-17 should be written in the same claim format as claims 1-6 with the identifier "original". An exception is applicant's claim 15, which has been amended; changing "A." to --a)--, "B." to --b)--. The parenthesis must say "(Amended)". "(Original-Amended)" is strongly recommended. If applicant further amends claim 15, the identifier must indicate that it has been "twice-amended", "thrice-amended", etc. The changes must be shown with underlining and brackets vis a vis the patent. Applicant's claim 15 submitted August 28, 1998 was almost in proper format, but failed to include the identifier.

Applicants claims 18-64 must be presented in completely underlined format as indicated above in the provided example of applicant's claim 58. Corrections are ALWAYS made vis a vis the patent, not the previous amendment. The identifiers "new", "new-amended" are strongly recommended for new claims.

In view that these requirements make it difficult to keep track of what has been changed in the claims that are newly presented (since the entire portion must be underlined at each presentation), applicant is required to indicate what is changed from the previous version of the claim in the "Remarks" portion of the amendment. See MPEP 1453 IV.D.

Recapture

Claims 18-64 are rejected under 35 U.S.C. 251 as being broadened in a reissue application filed within the two year statutory period.

This application contains claims 18-64 which are broader than the claims of the original patent. The reissue application was filed on August 28, 1998. The patent, US 5,554,121, issued on September 10, ~~1006~~ 1996. Accordingly, this reissue application was filed less than 2 years after grant of the patent. However, it is well established that a reissue application will not be permitted to recapture claimed subject matter deliberately canceled in the original application.

The original claims of the '121 patent contained claims 1-4 which were rejected in the first office action, mailed May 11, 1995, as being anticipated by Hamlin, U.S. 5,270,086.

Originally, filed cancelled claim 1 is as follows:

Claim 1. An intraluminal catheter having a shaft formed of an extruded engineering thermoplastic polymer having a tensile strength greater than about 10,000 psi, an elongation greater than about 50% and a tensile modulus greater than about 300,000 psi.

Applicant canceled this claim along with dependent claims 2-4 and prosecuted original claim 5, now patented claim 1.

1. (Patented, formerly claim 5) A balloon dilatation catheter comprising:

a) a proximal catheter shaft portion formed at least in part of an extruded engineering thermoplastic polymeric material with a tensile strength greater than 10,000 psi, an elongation greater than 50% and a tensile modulus greater than 300,000 psi, having proximal and distal ends and having a first inner lumen extending therein to the distal end;

b) a distal catheter shaft portion being more flexible than the proximal catheter shaft portion, having proximal and distal ends and a second inner lumen extending from the proximal end of the distal shaft portion to a location proximal to the distal end of the distal catheter shaft portion and being in fluid communication with the first inner lumen extending within the proximal catheter shaft portion; and

c) an expandable dilatation balloon on the distal catheter shaft portion having an interior in fluid communication with the second inner lumen extending within the distal shaft portion.

In the reissue application, applicant presents independent claims 18, 53 and 57, reproduced below.

18. (New) An intraluminal catheter for percutaneous insertion and transluminal advancement into a patient's vasculature, the catheter having a shaft comprising:

a) a proximal shaft portion formed at least in part of an extruded thermoplastic polymeric material with a tensile strength greater than 10,000 psi; and

b) a distal shaft portion that is more flexible than the proximal shaft portion.

53. (New) An intraluminal catheter for percutaneous insertion and transluminal advancement into a patient's vasculature, the catheter having a shaft comprising:

a) a proximal shaft portion formed at least in part of an extruded thermoplastic polymeric material with a tensile modulus greater than 300,000 psi, and

b) a distal shaft portion that is more flexible than the proximal shaft portion.

57. (New) An intraluminal catheter for percutaneous insertion and transluminal advancement into a patient's vasculature, the catheter having a shaft comprising:

a) a proximal shaft portion formed at least in part of an extruded thermoplastic polymeric material with an elongation greater than 50% and a tensile modulus greater than 400,000 psi; and

b) a distal shaft portion that is more flexible than the proximal shaft portion.

Claim 18 is broader in scope that canceled claim 1 as it omits the "elongation greater than about 50% and a tensile modulus greater than about 300,000 psi" claim limitations, and the requirement for a dilatation balloon.

Claim 53 is also broader than canceled claim 1. It also omits the "elongation greater than 50%", omits the "tensile strength greater than 10,000 psi" limitations, and omits the requirement for a dilatation balloon.

Claim 57 is also broader than canceled claim 1. Claim 57 omits the tensile strength greater than 10,000 psi, broadens the modulus "greater than about 300,000 psi" to "greater than about 400,000 psi," and omits the requirement for a dilatation balloon.

However, each of claim 18, 53 and 57 includes an added limitation regarding a proximal and distal shaft portion of the catheter, the distal shaft portion being more flexible than the proximal shaft portion.

Guidance may be found by comparing the instant situation to those discussed in Pannu v. Storz Instruments, Inc., 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001) and

Ex parte Eggert, 67 USPQ2d 1716 (BdPatApp&Int 2003). The various changed portions of the claims can be termed as a "surrender limitation" or "replacement limitation." Specifically, the mechanical properties of the catheter, i.e., the "elongation," "tensile modulus" or "tensile strength" characteristics from original canceled claim 1, which are omitted and/or broadened from claims 18, 53 and 57; are the "surrender limitation." Similarly, the added limitations regarding the distal and proximal portions of the catheter can be properly characterized as the "replacement limitation" as these were not set forth in original canceled claim 1.

As set forth by *Pannu* and *Eggert*, the reissue applicant can provide a "replacement limitation" for the "surrender limitation" only if the replacement limitation is "related" to the surrender limitation. Accordingly, the replacement limitation must narrow the claims in the same way that the surrender limitation narrowed the claims. It is insufficient that the claims be narrowed in a different area, even though if the replacement limitation had been added to originally prosecuted claim (here, canceled claim 1), it would have made the claim distinguishable from the prior art.

In other words, applicant might be tempted to argue that he could have amended claim 1 to include the proximal and distal portions in paper #5 filed August 24, 1998, and that this amendment would have eliminated Hamlin even if the recited mechanical properties (strength, modulus, elongation) had been in part omitted. Applicant may argue that since this amendment was not attempted and rejected, there is no recapture. However, this is not the test for recapture as set forth by *Pannu* and *Eggert*. The test is whether reciting the proximal and distal portions is an acceptable replacement limitation

for the omitted tensile strength, tensile modulus, elongation, and distal balloon limitations.

Clearly, these embodiments are not "related" within the outlines set forth by *Pannu* and *Eggert*. They are completely different aspects of the claimed intraluminal catheter. One limitation is directed to the mechanical properties (strength, modulus, elongation) of the polymeric material or the balloon, and one is directed to the portion of the catheter that contains the polymeric material and the portion which is more flexible. These are not related.

Applicant may also argue that the added limitations of the preamble, requiring that the catheter be "for percutaneous insertion and transluminal advancement into a patient's vasculature," however, again, this limitation is not related to the omitted mechanical properties of the catheter shaft.

Regarding the remaining dependent claims, these recite additional modest features such as the type of polymer, or adds limitations directed to the mechanical characteristics, and again, are not seen as proper replacement limitations for the portions of the deleted embodiments.

Accordingly, the claims are rejected for recapturing previously surrendered material.

Claim Rejections - 35 USC § 102

Claims 18-22, 26, 27, 31-48, 51-64 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Biesel, WO

94/01160 with reference to Muni et al., U.S. 5,316,706 and Bennett et al., U.S. 5,221,728.

Regarding claim 18, Biesel discloses an epidural catheter that is inserted intravascularly. Accordingly, Biesel discloses an intraluminal catheter for percutaneous insertion as claimed. See Biesel, page 2, lines 13-23. Biesel discloses that the stiff inner tube 12 may comprise PEEK (page 6, line 21). Distal portion 10 comprises the soft outer tube and anticipates the claimed more flexible distal shaft portion. Regarding the tensile strength, note page 7 and the tensile strengths listed therein. For PEEK, the tensile strength given is 13.6×10^3 psi, or 136,000 psi. Regarding the extruded limitation of the proximal shaft portion of claim 18, and noting the limitations of claims 51 and 52, see Biesel, page 10, line 12, which states that the epidural catheter can be constructed by known manufacturing processes "such as extrusion, drawing and the like." The examiner takes the position that this disclosure anticipates the claimed extruded proximal shaft.

In the alternative, Muni is cited to exemplify that the concept of extruding PEEK (column 4, line 33) angioplastic catheters to improve stiffness and pushability was well known when the Biesel invention was conceived in the early 90's. Accordingly, it would be obvious to one of ordinary skill in the art to extrude inner PEEK tube 12 of Biesel according to Muni so that the catheter exhibits improved pushability.

Regarding claims 31-34, 53+, note again page 7 and the tensile/flexural modulus disclosed therein. The third column discloses a PEEK tensile modulus of 0.51×10^6 psi, or 510,000 psi. Regarding claim 35, note that the PAEK polymer has a tensile strength

of 17.6 x 10^3 psi. Regarding claims 43-48 reciting the intended use, note that the Biesel catheter is inserted intravascularly, and there is discussion of preventing "blood vessel puncture" on page 5, line 13.

Regarding claims 20, 21, 37-42, 55-64, reciting the elongation at break, Biesel is silent as to the elongation at break data, which is not uncommon in the catheter art. However, the examiner takes the position that the Biesel catheter inherently possesses this characteristic as evidenced by Bennet. See, for example, Bennett, column 5, lines 45-60. A PEEK polymer was extruded and tested for modulus of elasticity, tensile strength and elongation at break. Note that the "modulus of elasticity" (also known as "flexural modulus", "tensile modulus," or more accurately, "tensile modulus of elasticity") cited by Bennett (2.4 GPa) is similar to that disclosed by Biesel, (3.5 GPa). The tensile strength of Bennett (107 MPa) is similar in range to that disclosed by Biesel (93.8 MPa). However, Biesel does not disclose an elongation at break. Bennett shows that a PEEK polymer with the same other characteristics of Biesel has an elongation at break of 156%. Accordingly, the examiner takes the position that Biesel inherently discloses the modest elongation at break claimed by applicant, being greater than 50% (claims 20, 57) and 60% (claim 37).

Claims 18, 24, 25 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Muni et al., U.S. 5,316,706 with reference to Biesel, WO 94/01160. Muni discloses the balloon angioplasty catheter (column 3, line 58) but fails to disclose the catheter properties. Biesel is cited to

exemplify that the ranges cited by applicant are known in the art for PEEK intravascular catheters. Accordingly, the examiner takes the position that Muni inherently discloses the claimed range. In the alternative, it would be obvious to one of ordinary skill in the art to make the Muni catheter with the tensile strength, tensile modulus as shown by Biesel so that the catheter would be able to traverse blood vessels without puncturing the walls of the blood vessels. Regarding claim 25, the feature recited is inherent for the operability of a balloon catheter.

Claim Rejections - 35 USC § 103

Claims 28-30, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biesel, WO 94/01160 with reference to Muni et al., U.S. 5,316,706. Regarding claims 28-30, applicant merely reverses the layering of the Biesel catheter, requiring that the proximal portion of the outer tubular member be made of the extruded material having the increased tensile strength. However, it is well established that the rearrangement of parts of *prima facie* obvious in the lack of a showing of criticality. See MPEP 2144.04 IV.C., entitled "Rearrangement of Parts," and note that the examiner may use legal precedent to provide the rationale supporting obviousness in this situation. In view that the examiner can find no evidence of unexpected results in the specification that would support patentability of this simple reversal, these claims must be rejected. Regarding claims 49 and 50, citing the length of the catheter, the Biesel length is recited on page 5, lines 29-35 as being a preferred length of 91.4 cm. Clearly, the Biesel catheter is not intended to be limited to this exact length. Further, it is well

established that catheter lengths vary dependent on patient need, and are selected according to the size of the patient. An infant would have a smaller sized catheter than a large adult.

Claims 23, 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muni et al., '706 in view of Beisel, WO '160 as applied to claims 18, 24 and 25 above, and further in view of Cornelius et al., US 5,423,754. Muni discloses a balloon angioplasty catheter but fails to detail the features commonly applied to these catheters. The Muni patent is primarily dedicated to the type of polymers and the method of making the catheter shaft. Applicant's claims 23, 1-17 point out the particular catheter structure desired. Cornelius exemplifies that the structure of inner and outer catheters, and the dilation balloon, the guide wire lumen, and with the various hard and soft areas are well known features in a balloon angioplasty catheter. It would be obvious to one of ordinary skill in the art to provide the Muni angioplasty catheter with angioplasty catheter features as shown by Cornelius, in order to make the Muni catheter operable for its intended purpose. An angioplasty catheter will not be operable, or will be barely operable (an imagined embodiment without a guide wire lumen), without the Cornelius features.

Response to Arguments

Applicant's arguments with respect to claims 1-64 have been considered but are moot in view of the new ground(s) of rejection.

This rejection is being made non-final so that applicant can respond to the rejection under 35 U.S.C. 251 and the modified prior art rejection.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Kennedy

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